

<b>Case Number:</b>	CM14-0146424		
<b>Date Assigned:</b>	09/12/2014	<b>Date of Injury:</b>	04/10/2013
<b>Decision Date:</b>	12/17/2014	<b>UR Denial Date:</b>	08/14/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/09/2014

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The expert reviewer is Board Certified in Anesthesiology, has a subspecialty in Pain Medicine, and is licensed to practice in Connecticut. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

After careful review of the medical records, this is a 49-year-old male with complaints of constant LBP. The date of injury is 04/10/13 and the mechanism of injury was not documented. At the time of request for Cyclobenzaprine Hydrochloride Tablets 7.5mg #120, Ondansetron ODT Tablets 8mg #30, Omeprazole Delayed-Release Capsules 20mg #120, and Tramadol Hydrochloride ER 150mg #90, there are subjective (constant LBP with radiation to lower extremities, aggravated by bending, lifting, twisting, pushing, pulling, prolonged sitting and standing, and walking with multiple blocks, characterized as sharp, 7/10), objective (on L-spine exam, palpable paravertebral muscle tenderness with spasm, positive seated nerve root test, guarded and restricted standing flexion and extension on ROM, tingling and numbness in the posterior leg and lateral foot in SI dermatomal pattern, strength in ankle plantar flexors was 4, SI innervated muscle, asymmetric ankle reflexes.), findings, imaging/other findings (none documented), current medications (none documented), diagnoses (lumbar disc disorder), treatment to date (none documented). Current medications, diagnostic studies, and treatment to date reports were not documented in the clinical records submitted with this request. The request for Cyclobenzaprine Hydrochloride Tablets 7.5mg #120, Ondansetron ODT Tablets 8mg #30, Omeprazole Delayed-Release Capsules 20mg #120, and Tramadol Hydrochloride ER 150mg #90 was denied on 08/14/14.

### IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

**Cyclobenzaprine Hydrochloride Tablets 7.5mg #120: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antispasmodics Page(s): 64.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Flexeril/muscle relaxants Page(s): 41, 63-66.

**Decision rationale:** According to the guidelines, antispasmodics are used to decrease muscle spasms. Cyclobenzaprine is recommended as an option, using a short course. The medical records do document the presence of substantial muscle spasm on exam. Chronic use of muscle relaxants is not recommended by the guidelines; however, the requesting physician documented use of this medication for acute flare up muscle spasm as needed. However, the request for Cyclobenzaprine Hydrochloride Tablets 7.5mg #120 is not considered medically necessary as there is no specified duration of treatment and the amount requested is not supporting a short course of treatment. Therefore the request is not medically necessary.

**Ondansetron ODT Tablets 8mg #30:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability GUIDELINES

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain(Chronic), Ondansetron (Zofran)

**Decision rationale:** The CA MTUS guidelines have not addressed the issue of dispute. According to the ODG, Antiemetics (for opioid nausea) is not recommended for nausea and vomiting secondary to chronic opioid use. Ondansetron is a serotonin 5-HT<sub>3</sub> receptor antagonist. It is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment. It is also FDA-approved for postoperative use. Acute use is also FDA-approved for gastroenteritis. Furthermore, there is no documentation of nausea refractory to first line treatments. In the absence of documented symptoms of nausea and vomiting secondary to chemotherapy and radiation treatment or any signs and symptoms of acute gastroenteritis, the request for Ondansetron ODT Tablets 8mg #30 is not medically necessary.

**Omeprazole Delayed-Release Capsules 20mg #120:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs ,GI Symptoms &Cardiovascular Risk Page(s): 68-69.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs/PPI Page(s): 67-73 (68).

**Decision rationale:** According to the CA MTUS, Omeprazole"PPI" is recommended for Patients at intermediate risk for gastrointestinal events. The CA MTUS guidelines state PPI medications such as Omeprazole (Prilosec) may be indicated for patients at risk for gastrointestinal events,

which should be determined by the clinician: 1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Treatment of dyspepsia secondary to NSAID therapy recommendation is to stop the NSAID, switch to a different NSAID, or consider H2-receptor antagonists or a PPI. The guidelines recommend GI protection for patients with specific risk factors; the medical records in this case do state the patient is at risk for GI events / risks as stated above. Therefore, the medical necessity of the request for Omeprazole Delayed-Release Capsules 20mg #120 is established at this time. The request is medically necessary.

**Tramadol Hydrochloride ER 150mg #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 93-94.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-84. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain(Chronic), Tramadol

**Decision rationale:** According to the CA MTUS Guidelines, Tramadol (Ultram) is a centrally acting synthetic opioid analgesic and it is not recommended as a first-line oral analgesic (as it is a schedule IV opioid), it is indicated for moderate to severe pain. The CA MTUS Guidelines indicate "four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids; pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors)." The guidelines state opioids may be continued: (a) If the patient has returned to work and (b) If the patient has improved functioning and pain. The medical records have not demonstrated the requirements for continued opioid therapy have been met. There is no evidence of urine drug screen to monitor the patient's compliance as well as any documentation for surveillance of aberrant behavior/drug seeking, establishment of one prescriber/pain contract, pill counts, etc. There is no evidence of return to work in this injured worker. There is little to no documentation of pain level and function with prior use. Therefore, the medical necessity of Tramadol Hydrochloride ER 150mg #90 has not been established per guidelines. The request is not medically necessary.